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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,930	03/17/2005	Shou Takashima	P25687	2173

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EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/23/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/501,930	TAKASHIMA ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8-10 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8-10 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Application Status

In response to the Office Action mailed on 06/15/2006, applicants' filed a response and amendment received on 12/07/2006. Said amendment, amended claims 1-2, 8-10 and 15, and canceled claims 3-7 and 11-14. Thus, claims 1-2, 8-10 and 15 are pending in the instant Office Action and are now under consideration.

Objections and rejections not reiterated from the previous action are hereby withdrawn.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a 371 of PCT/JP03/00883 filed on 01/30/2003 and claims the priority date of Japanese applications 2002-21159 filed on 01/30/2002 and 2002-122673 filed on 04/24/2002. Examiner notes that the English translation for the Japanese applications have been provided on 11/27/06.

Withdrawn- Claim Rejections 35 USC § 101

Previous rejection of claims 1-2, 8-10 and 15 under 35 U.S.C. 101 is withdrawn in view of the applicants' cancellation of claims 3-7 and 11-14 and amendment of claims 1-2, 8-10 and 15.

Withdrawn- Claim Rejections 35 USC § 112

Previous rejection of claims 2 and 9 under 35 U.S.C. 112, second paragraph is withdrawn in view of the applicants' cancellation of claims 3-7 and 11-14 and amendment of claims 2 and 9.

Maintained- Restriction

Restriction requirement is maintained, as the non-elected sequences require a new search and analysis of results.

Claim Objections

Claims 2, 8-9 and 15 are objected to, due to the following informality: Claims 2, 8-9 and 15 contain non-elected subject matter, i.e., SEQ ID NOs. Appropriate correction is required.

Maintained- Claim Rejections 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated of a polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1, encoded by a polynucleotide of SEQ ID NO: 2 or comprising the nucleotide residues 77-1270 of SEQ ID NO: 2 and having O-glycan α2,8-sialyltransferase activity, does not reasonably provide enablement for any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase and any signal peptide and having O-glycan α2,8-sialyltransferase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1and 10 are so broad as to encompass for any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase and any signal peptide and having O-glycan α2,8-sialyltransferase activity. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and encoding polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated polypeptide with SEQ ID NO: 1 and having the O-glycan α2,8-sialyltransferase activity encoded by a polynucleotide of SEQ ID NO: 2, but provides no guidance with regard to the making of

variants and mutants from any source or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides and encoding polynucleotides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claim, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims which encompass for any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase and any signal peptide and having O-glycan α2,8-sialyltransferase activity, because the specification does not establish: (A) regions of the

protein/polynucleotide structure which may be modified without affecting the activity of encoded O-glycan α2,8-sialyltransferase activity; (B) the general tolerance of the polypeptide and the polynucleotide encoding O-glycan α2,8-sialyltransferase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polypeptides and encoding polynucleotides with an enormous number of modifications. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides and encoding polynucleotides of any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase with any signal peptide and having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicants' have responded to the above rejections with the response, that cancellation of certain claims and amendments to delete sections of claims relating to " a

deletion, substitution, and/or addition of one or more several amino acids" of SEQ ID NOS: 1 or 3" and therefore request for withdrawal of the rejection in the light of the amendments.

Applicants' arguments have been considered and found to be non-persuasive for the following reasons. The scope the claims 1and 10 as written, without structural limitations still continues to read on any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase and any signal peptide and having O-glycan α2,8-sialyltransferase activity.

Claims 8 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because, while claims 8 and 15 are being enabling for use of an isolated host cell transformed with the synthetic nucleic acid for a method of producing O-glycan α2,8-sialyltransferase, does not reasonably provide enablement for use of transgenic multi-cellular organisms or host cells within a multi-cellular organism that have been transformed with the synthetic nucleic acid for a method of producing O-glycan α2,8-sialyltransferase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 8 and 15 are so broad as to encompass expression of a polypeptide in transgenic multi-cellular organisms and host cells transformed with specific nucleic acids, including cells in *in vitro* culture as well as within any multi-cellular organism for

a method of producing O-glycan α2,8-sialyltransferase. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to extremely large number of transformed organisms broadly encompassed by the claims. While methods for transforming cells *in vitro* are well known in the art, methods for successfully transforming cells within complex multi-cellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within the multi-cellular organism are unlikely to be applicable to transformation of other types of multi-cellular organism as multi-cellular organisms vary widely. However, in this case the disclosure is limited to only a method of producing O-glycan α2,8-sialyltransferase isolated host cells *in vitro*. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multi-cellular organism for the production of polypeptide. The scope of claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA)). Without sufficient guidance, expression of genes in a particular host cell and having the desired biological characteristics is unpredictable, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F. 2d 731, 8 USPQ 2nd 1400 (Fed. Cir., 1988). It is suggested that the applicants limit the claims to "An isolated host cell ...".

Written Description

Claims 1 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 10, as interpreted, are directed to a genus polypeptides comprising any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase and any signal peptide and having O-glycan α2,8-sialyltransferase activity.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the

genus, one must describe a sufficient variety of species to reflect the variation within the genus.

In the instant case, there is no structure correlated to associated function recited in claims with regard to the members of the genus of polypeptides comprising any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase and any signal peptide and having O-glycan α2,8-sialyltransferase activity. While The specification discloses the isolation of a polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1 encoded by a polynucleotide of SEQ ID NO: 2 or comprising the nucleotide residues 77-1270 of SEQ ID NO: 2 and having O-glycan α2,8-sialyltransferase activity, an expression vector comprising said polynucleotide and method of making said polypeptide, it fails to provide any information as to the structure associated with function for the genus of polypeptides claimed i.e., comprising any isolated O-glycan α2,8-sialyltransferase from any source including variants, mutants and recombinants or any isolated extracellular secretory protein from any source comprising a polypeptide portion which is an active domain of any O-glycan α2,8-sialyltransferase and any signal peptide and having O-glycan α2,8-sialyltransferase activity with no structural limitations.

Due to the fact that the specification only discloses the structure of an enzymatically active and isolation of a polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1 encoded by a polynucleotide of SEQ ID NO: 2 or comprising the nucleotide residues 77-1270 of SEQ

ID NO: 2 and having O-glycan α2,8-sialyltransferase activity, an expression vector comprising said polynucleotide and method of making said polypeptide, and the lack of description of any additional species/variants/mutants/recombinants from any source by any relevant, identifying characteristics or properties, one of skill in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Applicants' have responded to the above rejections with the response, that cancellation of certain claims and amendments to delete sections of claims relating to " a deletion, substitution, and/or addition of one or more several amino acids" of SEQ ID NOS: 1 or 3" and therefore request for withdrawal of the rejection in the light of the amendments.

Applicants' arguments have been considered and found to be non-persuasive for the following reasons. Claims 1 and 10 as written, have no structural limitations and are directed to a genus of polypeptides from any source including mutants, variants and recombinants of the same. The specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of said enzymes. Furthermore, it is well known in the art that structurally related molecules may not possess similar function including desired specificity for substrates and enzyme kinetics and conversely functionally similar molecules may not share similar structural features or significant homology. Therefore, given this lack of description of representative species encompassed by the genus of the claims, the specification fails to

sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Maintained-Claim Rejections 35 USC § 102

Claims 2, 8-9 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Takashima et al., (JBC., 2002, Vol. 277 (27): 24030-24038, on line publication April 29, 2002). Although an English translation has been provided for foreign priority document JP 2002-21159 filed on 01/30/2002 and is sufficient to overcome the rejections of claims 1 and 10, claims 2, 8-9 and 15 recite subject matter not supported by the foreign priority document (SEQ ID NOs: 3 and 4) and therefore benefit of the filing date of the foreign priority document is not granted to said claims.

Maintained-Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawai et al., (Nature 2001, Vol. 409: 685-690). Claims 1-2 and 9-10, are directed to any isolated O-glycan α2,8-sialyltransferase from any sources including variants, mutants and recombinants or to an isolated of a polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1, encoded by a polynucleotide of SEQ ID NO: 2 or comprising the nucleotide residues 77-1270 of SEQ

ID NO: 2 and having O-glycan α2,8-sialyltransferase activity, a recombinant expression vector comprising the gene encoding the polypeptide of SEQ ID NO: 1, a host cell and method of producing the polypeptide. Kawai et al., teach the isolation of a polynucleotide (see supplementary Table 4, section C. InterPro Motifs of RIKEN clones, InterPro ID NO: IPR001675, annotated as sialyltransferase) from mouse that has 100% homology to SEQ ID NO: 2 of the instant application (see sequence alignment provided) and predicted to encode a polypeptide with sialyltransferase activity having 100% homology to the polypeptide of SEQ ID NO: 1 of the instant application (see sequence alignment provided). The reference is silent on the substrate specificity of the annotated polypeptide i.e., O-glycan α2,8-sialyltransferase having substrate specificity wherein substrates are glycoconjugates having Siaα2,3(6) Gal structure, however examiner takes the position, that by virtue of 100% homology to SEQ ID NO: 1 of the instant application, the polynucleotide isolated by Kawai et al., and the encoded polypeptide inherently posses the O-glycan α2,8-sialyltransferase having substrate specificity wherein substrates are glycoconjugates having Siaα2,3(6) Gal structure. Furthermore, the reference also teaches the recombinant expression constructs and host cells (Methods section, page 688) and therefore, Kawai et al., anticipate claims 1-2 and 8-10 as written.

Applicants' have traversed the rejections with the arguments, "said references have disclosed the cDNA sequence and the encoded polypeptide has 100% sequence homology to SEQ ID NO: 1 but the cited prior art reference does not disclose any function of protein encoded by said cDNA and the substrate specificity. Accordingly the prior art does not provide all the elements of the claimed invention and have requested the withdrawal of rejection of claims 1-2 and 9-10".

Applicants arguments have been considered and found to be non-persuasive as all the said prior art references have provided the **isolated physical cDNA** with encoding polypeptide sequence and MPEP Chapter 2100-Patentability, clearly states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.< See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103".

Claim Rejections 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Kawai et al., (Nature 2001, Vol. 409: 685-690). Claims 8 and 15 are directed to a method of producing a polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1, encoded by a polynucleotide of SEQ ID NO: 2 or comprising the nucleotide residues 77-1270 of SEQ ID NO: 2 and having O-glycan α2,8-sialyltransferase activity, a recombinant expression vector comprising the gene encoding the polypeptide of SEQ ID NO: 1 and a host cell. The many advantages of recombinant production of useful proteins are well known within the art as are recombinant methods of obtaining the necessary genes. These advantages include the ability to produce much larger quantities of the protein, being able to produce the protein in more easily handled organisms, reducing the number of steps necessary for the purification of a protein and producing the protein in a purer form by using an organism that does not include naturally occurring contaminants of the protein. As such the disclosure of a useful protein, said polypeptide comprising the sequence of SEQ ID NO: 1 and encoded by a polynucleotide sequence of SEQ ID NO: 2, such as that of Kawai et

al., (*supra*) clearly suggests to the ordinary skilled artisan, to transform any suitable host cell with an expression vector comprising said polynucleotide, as such a gene would be useful to produce large quantities of the protein. Therefore, it would have been obvious to one of ordinary skill in the art to isolate and express the gene encoding the sialyltransferase disclosed by Kawai et al. using well known recombinant methods for the isolation of such gene, insertion of the isolated gene into an expression vector, transformation into a suitable host, expression of the encoded protein and collecting the protein from the culture.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

1) Amended claims 2, 8-9 and 15 are objected to, due to the following informality: Claims 2, 8-9 and 15 contain non-elected subject matter, i.e., SEQ ID NOs.

2) Amended claims 1, 8, 10 and 15 are rejected under 35 U.S.C. first paragraph for written description and enablement.

3) Amended claims 1-2 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawai et al., (Nature 2001, Vol. 409: 685-690).

4) Amended claims 2, 8, 9 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Takashima et al., (JBC., 2002, Vol. 277 (27): 24030-24038, on line publication April 29, 2002)

5) Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Kawai et al., (Nature 2001, Vol. 409: 685-690).

Conclusion

None of the claims are allowable. Claims 1-2, 8-10 and 15 are rejected/objected for the reasons identified in the Rejections/objections and Summary sections of this Office Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652
Feb. 01, 2007.

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600